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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,936	03/16/2001	Tony N. Frudakis	210121.419CIP	7264

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/810,936	Applicant(s) FRUDAKIS ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 12-22* is/are pending in the application.

4a) Of the above claim(s) *1-4, 6-10, and 12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4,6-10 and 12-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Attachment for PTO-948* .

DETAILED ACTION

1. Applicant's election without traverse of Group III in Paper No. 9, filed August 01, 2002, is acknowledged. Further, the amendment of canceling claims 5 and 11 of Group III and the replacement of claims 5 and 11 with claims 18 – 22 is acknowledged.

2. Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is mailed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

3. Claims 18-22 are examined on the merits.

PRIORITY

4. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. Accordingly, examined claims 18-22 will be granted the priority date of May 24, 2000, corresponding to U.S. Serial Number 09/577,505.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

5. Claims 18 - 22 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification is such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount direction presented, (3) the presence or absence or working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

7. In case of claims 18 - 22, the applicant does not provide any disclosures within the specification that would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. Claims 18 – 22 are broadly drawn to an isolated antibody, or antigen-binding fragment thereof, that specifically binds to a B305D polypeptide. The applicant discussed in Example 7 (pages 105 – 108) the preparation and characterization of antibodies against breast tumor polypeptides. However, the specification fails to support the claimed invention that an isolated antibody specifically binds to B305D.

Disclosed in the specification, the antibodies raised against a B305D polypeptide are polyclonal antibodies. The B305D polypeptide contains "multiple epitopes, exposure of an animal to an antigen usually stimulates formation of several different B-lymphocyte clones, each producing a different antibody; a mixture of antibodies that recognize different epitopes on the same antigen is said to be polyclonal" (Lodish et. al). Polyclonal antibodies have a propensity to

recognize a variety of different antigenic sites including sites that are not related to the B305D polypeptide. In most common cases, polyclonal antibodies recognize other antigens in addition to the polypeptide used to generate them. This phenomenon usually results in high background staining in immunohistochemical analysis or the appearance of extract bands in Western Blots. It is a general practice to purify polyclonal antibodies via liquid chromatography purification or develop monoclonal antibodies to peptides of known short amino acid sequences to eliminate non-specific immunological interactions. However, antibody purification or raising monoclonal antibodies to a specific polypeptide, albeit helpful, but does not always eliminate non-specific immunological interactions. It is, therefore, concluded that the specification fails to support the claim that an isolated antibody binds specifically to B305D polypeptide. Further, the applicant does not provide any disclosures within the specification that would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

8. Claims 19 – 21 broadly drawn to an isolated antibody, or antigen-binding fragment thereof, that binds to a polypeptide having an amino acid sequence 80%, 90% or 95% identical to the amino acid sequence of SEQ ID NO:304. The applicant discusses the variants of the polypeptide compositions and the polypeptide fragments and variants that are immunologically reactive with an antibody (page 14, lines 1 – 8). However, the specification does not reasonably provide enablement for an isolated antibody, or antigen-binding fragment thereof, that binds to a polypeptide having an amino acid sequence 80%, 90% or 95% identical to the amino acid sequence of SEQ ID NO:304. It is unclear as to how it would be possible to predict with accuracy that the immunological interactions correspond to an amino acid sequence with 80%, 90% or 95% identity to SEQ ID NO:304, respectively. Further, there is not any guidance as how

a person skill in the art of making antibodies to distinguish immunologic interactions between an antibody to polypeptides that are similar to the polypeptide of SEQ ID NO:304 in an *in vivo* environment. Therefore, the applicant does not provide any disclosures within the specification that would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

CLAIM REJECTIONS – 35 USC §102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(e) that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 18 - 22 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Xu et. al. (P/N 6,329,505).

11. The above U.S. Patent (P/N 6,329,505) discloses an antibody against prostate-specific polypeptides (Column 66, lines 49 – 50) wherein the said polypeptide is a splice form of B305D (column 58, lines 1 – 16) and its expression is high in prostate tumor and low in normal bone marrow (Column 58, lines 17 – 24). Xu discloses an amino acid sequence SEQ ID NO:378 (P/N 6,329,505) that is at least 80% identity to SEQ ID NO:304. The polypeptide sequence of SEQ ID NO:304 was used to search the Issue Patents Amino Acid database and it resulted in sequence with SEQ ID NO:378 (P/N 6,329,505) having 100% identity to SEQ ID NO:304. Further, polypeptide sequence SEQ ID NO:378 (P/N 6,329,505) is a prostate specific protein (Column 2,

lines 6 – 22) and is detected by antibodies raised against prostate-specific polypeptides. Also, Xu discloses a pharmaceutical composition comprises of an antibody or antigen binding fragment thereof that specifically binds to a prostate-specific protein and physiologically acceptable carrier (Column 2, lines 48 – 52).

12. No Claim is allowed.

13. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
9/17/02